113TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
113–478

NEWBORN SCREENING SAVES LIVES REAUTHORIZATION ACT OF 2014

JUNE 19, 2014.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 1281]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1281) to amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Newborn Screening Saves Lives Reauthorization Act of 2014".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND FOLLOWUP FOR HERITABLE DISORDERS.

Section 1109 of the Public Health Service Act (42 U.S.C. 300b–8) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1)—

(i) by striking "subsection (j)" and inserting "section 1117"; and

(ii) by striking "and in consultation with the Advisory Committee" and inserting "and taking into consideration the expertise of the Advisory Committee";

(B) by amending paragraph (2) to read as follows:

"(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening, counseling, and training in—

"(A) relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

"(B) the importance of the timeliness of collection, delivery, receipt, and screening of specimens; and

"(C) sharing of medical and diagnostic information with providers and families;";

(C) in paragraph (3), by striking "and" at the end;

(D) in paragraph (4)—

(i) by striking "treatment" and inserting "followup and treatment"; and

(ii) by striking the period and inserting "; and"; and

(E) by adding at the end the following:

"(5) to improve the timeliness of—

"(A) the collection, delivery, receipt, and screening of specimens; and

"(B) the diagnosis of heritable disorders in newborns.";

(2) in subsection (c), by striking "application submitted for a grant under subsection (a)(1)" and inserting "application for a grant under this section";

(3) in subsection (h), by striking "application submitted under subsection (c)(2)" each place it appears and inserting "application for a grant under this section"; and

(4) by striking subsection (j) (relating to authorization of appropriations).

SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING AND FOLLOWUP PROGRAMS.

Section 1110 of the Public Health Service Act (42 U.S.C. 300b–9) is amended—

(1) in the section heading, by inserting "**AND FOLLOWUP**" after "**CHILD SCREENING**";

(2) in subsection (a), by striking "of screening," and inserting ", including with respect to timeliness, of screening, followup,";

(3) in subsection (b)—

(A) in paragraph (1)—

(i) by striking "counseling, testing" and inserting "treatment, counseling, testing, followup,"; and

(ii) by inserting before the semicolon the following: ", including, as appropriate, through the assessment of health and development outcomes for such children through adolescence";

(B) in paragraph (2)—

(i) by striking "counseling, testing" and inserting "treatment, counseling, testing, followup,";

(ii) by inserting "in a timely manner" after "in newborns and children"; and

(iii) by striking "or" at the end;

(C) in paragraph (3), by striking the period at the end and inserting a semicolon; and

(D) by adding at the end the following:

"(4) methods that may be identified to improve quality in the diagnosis, treatment, and disease management of heritable disorders based on gaps in services or care; or

"(5) methods or best practices by which the eligible entities described in section 1109 can achieve in a timely manner—

"(A) collection, delivery, receipt, and screening of newborn screening specimens; and

"(B) diagnosis of heritable disorders in newborns."; and

(4) by striking subsection (d) (relating to authorization of appropriations).

SEC. 4. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

Section 1111 of the Public Health Service Act (42 U.S.C. 300b–10) is amended—

(1) in subsection (b)—

(A) by redesignating paragraphs (4) through (6) as paragraphs (6) through (8), respectively;

(B) by inserting after paragraph (3), the following:

"(4) provide technical assistance, as appropriate, to individuals and organizations regarding the submission of nominations to the uniform screening panel, including prior to the submission of such nominations;

"(5) take appropriate steps, at its discretion, to prepare for the review of nominations prior to their submission, including for conditions for which a screening method has been validated but other nomination criteria are not yet met, in order to facilitate timely action by the Advisory Committee once such submission has been received by the Committee;";

(C) in paragraph (6) (as so redesignated), by inserting ", including the cost" after "public health impact"; and

(D) in paragraph (8) (as so redesignated)—

(i) in subparagraph (A), by striking "achieve rapid diagnosis" and inserting "achieve best practices in rapid diagnosis and appropriate treatment";

(ii) in subparagraph (D), by inserting before the semicolon ", including information on cost and incidence";

(iii) in subparagraph (J), by striking "and" at the end;

(iv) in subparagraph (K), by striking the period and inserting "; and"; and

(v) by adding at the end the following:

"(L) the timeliness of collection, delivery, receipt, and screening of specimens to be tested for heritable disorders in newborns in order to ensure rapid diagnosis and followup.";

(2) in subsection (d)—

(A) in paragraph (1)—

(i) by striking "180" and inserting "120"; and

(ii) by adding at the end the following: "If the Secretary is unable to make a determination to adopt or reject such recommendation within such 120-day period, the Secretary shall notify the Advisory Committee and the appropriate committees of Congress of such determination together with an explanation for why the Secretary was unable to comply within such 120-day period, as well as a plan of action for consideration of such pending recommendation.";

(B) by striking paragraph (2);

(C) by redesignating paragraph (3) as paragraph (2); and

(D) by adding at the end the following:

"(3) DEADLINE FOR REVIEW.—For each condition nominated to be added to the recommended uniform screening panel in accordance with the requirements of this section, the Advisory Committee shall review and vote on the nominated condition within 9 months of the date on which the Advisory Committee referred the nominated condition to the condition review workgroup.";

(3) by redesignating subsections (f) and (g) as subsections (g) and (h), respectively;

(4) by inserting after subsection (e) the following new subsection:

"(f) MEETINGS.—The Advisory Committee shall meet at least 4 times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the Chair.";

(5) by amending subsection (g) (as so redesignated) to read as follows:

"(g) CONTINUATION OF OPERATION OF COMMITTEE.—

"(1) IN GENERAL.—Notwithstanding section 14 of the Federal Advisory Committee Act, the Advisory Committee shall continue to operate through the end of fiscal year 2019.

"(2) CONTINUATION IF NOT REAUTHORIZED.—If at the end of fiscal year 2019 the duration of the Advisory Committee has not been extended by statute, the Advisory Committee may be deemed, for purposes of the Federal Advisory Committee Act, an advisory committee established by the President or an officer of the Federal Government under section 9(a) of such Act."; and

(6) by striking subsection (h) (relating to authorization of appropriations), as redesignated by paragraph (3).

SEC. 5. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

Section 1112 of the Public Health Service Act (42 U.S.C. 300b–11) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking "and" at the end;

(B) in paragraph (3)—

(i) by striking "data" and inserting "information"; and

(ii) by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new paragraphs:

"(4) maintain current information on the number of conditions for which screening is conducted in each State; and

"(5) disseminate available evidence-based guidelines related to diagnosis, counseling, and treatment with respect to conditions detected by newborn screening.";

(2) in subsection (b)(4)(D), by striking "Newborn Screening Saves Lives Act of 2008" and inserting "Newborn Screening Saves Lives Reauthorization Act of 2014";

(3) in subsection (c)—

(A) by striking "developing the clearinghouse" and inserting "carrying out activities"; and

(B) by striking "clearinghouse minimizes duplication and supplements, not supplants" and inserting "activities minimize duplication and supplement, not supplant"; and

(4) by striking subsection (d) (relating to authorization of appropriations).

SEC. 6. LABORATORY QUALITY AND SURVEILLANCE.

Section 1113 of the Public Health Service Act (42 U.S.C. 300b–12) is amended—

(1) in the section heading, by inserting "**AND SURVEILLANCE**" before the period;

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "and in consultation with the Advisory Committee" and inserting "and taking into consideration the expertise of the Advisory Committee"; and

(B) in paragraph (1), by inserting "timeliness for processing such tests," after "newborn-screening tests,"; and

(3) by striking subsection (b) (relating to authorization of appropriations) and inserting the following:

"(b) SURVEILLANCE ACTIVITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, may provide, as appropriate, for the coordination of surveillance activities, including—

"(1) through standardized data collection and reporting, as well as the use of electronic health records; and

"(2) by promoting data sharing regarding newborn screening with State-based birth defects and developmental disabilities monitoring programs.".

SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

Section 1114 of the Public Health Service Act (42 U.S.C. 300b–13) is amended—

(1) in subsection (c), by striking "the Administrator, the Director of the Agency for Healthcare Research and Quality," and inserting "the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs,"; and

(2) by striking subsection (e) (relating to authorization of appropriations).

SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.

Section 1115(a) of the Public Health Service Act (42 U.S.C. 300b–14(a)) is amended—

(1) by striking "consortia" and inserting "consortium"; and

(2) by adding at the end the following: "The plan shall be updated as needed and at least every five years.".

SEC. 9. HUNTER KELLY RESEARCH PROGRAM.

Section 1116 of the Public Health Service Act (42 U.S.C. 300b–15) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (B), by striking "; and" and inserting a semicolon;

(B) by redesignating subparagraph (C) as subparagraph (E); and

(C) by inserting after subparagraph (B) the following:

"(C) providing research findings and data for newborn conditions under review by the Advisory Committee on Heritable Disorders in Newborns and Children to be added to the recommended uniform screening panel;

"(D) conducting pilot studies on conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children to ensure that screenings are ready for nationwide implementation; and"; and

(2) in subsection (c), by striking "of the National Institutes of Health Reform Act of 2006".

SEC. 10. AUTHORIZATION OF APPROPRIATIONS.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.) is amended by adding at the end, the following:

"SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR NEWBORN SCREENING PROGRAMS AND ACTIVITIES.

"There are authorized to be appropriated—

"(1) to carry out sections 1109, 1110, 1111, and 1112, $11,900,000 for each of fiscal years 2015 through 2019; and

"(2) to carry out section 1113, $8,000,000 for each of fiscal years 2015 through 2019.".

SEC. 11. REPORTS TO CONGRESS.

(a) GAO REPORT ON TIMELINESS OF NEWBORN SCREENING.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives concerning the timeliness of screening for heritable disorders in newborns.

(2) CONTENTS.—The report submitted under paragraph (1) shall include the following:

(A) An analysis of information regarding the timeliness of newborn screening, which may include the time elapsed from birth to specimen collection, specimen collection to receipt by laboratory, specimen receipt to reporting, reporting to followup testing, and followup testing to confirmed diagnosis.

(B) A summary of any guidelines, recommendations, or best practices available to States and health care providers intended to support a timely newborn screening system.

(C) An analysis of any barriers to maintaining a timely newborn screening system which may exist and recommendations for addressing such barriers.

(b) REPORT BY SECRETARY.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall—

(A) not later than 1 year after the date of enactment of this Act, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on activities related to—

(i) newborn screening; and

(ii) screening children who have or are at risk for heritable disorders; and

(B) not less than every 2 years, submit to such committees an updated version of such report.

(2) CONTENTS.—The report submitted under this subsection shall contain a description of—

(A) the ongoing activities under sections 1109, 1110, and 1112 through 1115 of the Public Health Service Act; and

(B) the amounts expended on such activities.

PURPOSE AND SUMMARY

H.R. 1281, the "Newborn Screening Saves Lives Reauthorization Act of 2014," was introduced on March 20, 2013, by Rep. Lucille Roybal-Allard (D–CA) and Rep. Mike Simpson (R–ID) and referred to the Committee on Energy and Commerce.

The bill would reauthorize the Newborn Screening Saves Lives Act of 2008 to continue Federal support for newborn screening activities.

BACKGROUND AND NEED FOR LEGISLATION

Newborn screening is the practice of testing newborns for certain disorders that are treatable, but not clinically evident at birth. The baby may look healthy, but have certain genetic and metabolic conditions that can affect the child's long-term health or survival. Newborn screening was introduced as a public health program in the early 1960s. Every State now requires newborn screening, but each State determines that tests are required.[1]

Federal programs to improve the ability of States to provide screening for heritable disorders were first enacted in the Children's Health Act of 2000 and included the establishment of a Federal advisory committee.[2] In February 2003, the U.S. Department of Health and Human Services chartered the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) to make recommendations to the Secretary that would standardize newborn screening programs in the U.S.[3] In 2008, Congress enacted the Newborn Screening Save Lives Act of 2007, which amended the Public Health Service Act to reauthorize and expand the duties of the Advisory Committee, continue the grant program, provide for quality assurance for screening laboratories, establish a clearinghouse of current information on newborn screening, continuation of research on new treatments, and require an annual report.[4]

H.R. 1281 would reauthorize the "Newborn Screening Save Lives Act of 2007" and further strengthen newborn screening activities. The bill clarifies the need for health care professionals and laboratory personnel to be trained in the latest technology related to newborn screening, understand the importance of timeliness in the collection, delivery, receipt, and screening of specimens, and share medical and diagnostic information with providers and families. The bill also would encourage the Advisory Committee to take appropriate steps to timely review and vote on nominated conditions. Finally, the bill would shorten the time for the Secretary to adopt or reject a recommendation from the Advisory Committee to 120 days.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 1281 on November 20, 2013, and received testimony from:

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[1] http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reports recommendations/reports/sachdnc2011report.pdf.

[2] http://www.gpo.gov/fdsys/pkg/PLAW-106publ310/html/PLAW-106publ310.htm.

[3] http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reports recommendations/reports/sachdnc2011report.pdf.

[4] https://www.govtrack.us/congress/bills/110/s1858.

- Marsha Ford, MD, FACMT, President, American Association of Poison Control Centers;
- Edward R.B. McCabe, MD, PhD, Senior Vice President and Chief Medical Officer, Office of Medicine and Health Promotion, March of Dimes Foundation;
- Laura Crandall, Co-Founder, Sudden Unexplained Death In Childhood Program, CJ Foundation for SIDS;
- Robert Mt. Joy, CEO, Cornerstone Care Inc.;
- Drew Nagele, Board of Directors, Brain Injury Association of America;
- Pat Smith, President, Lyme Disease Association, Inc.; and,
- Steven J. Stack, Immediate Past Chair, Board of Trustees, American Medical Association.

COMMITTEE CONSIDERATION

On February 27, 2014, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 1281 to the full Committee, as amended, by a voice vote. On April 3, 2014, the Energy and Commerce Committee met in open markup session and approved H.R. 1281, as amended, by unanimous consent.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering approved H.R. 1281. A motion by Mr. Upton to order H.R. 1281 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing on H.R. 1281 and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(1) of rule XIII of the House of Representatives, the goal of H.R. 1281 is to reauthorize the Newborn Screening Saves Lives Act of 2008 to continue Federal activities that assist States in improving their newborn screening programs, supporting parent and provider newborn screening education, and ensuring laboratory quality and surveillance.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1281 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 1281 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 6, 2014.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1281, the Newborn Screening Saves Lives Reauthorization Act of 2014.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Santiago Vallinas.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 1281—Newborn Screening Saves Lives Reauthorization Act of 2014

Summary: H.R. 1281 would amend the Public Health Service Act to reauthorize grant programs and other initiatives to promote expanded screening of newborns and children for heritable disorders. Authority to operate those programs expired at the end of fiscal year 2013. However, the Congress appropriated funds for fiscal year 2014 to continue the programs in 2014.

CBO estimates that implementing H.R. 1281 would cost $80 million over the 2015–2019 period, assuming appropriation of the necessary amounts. H.R. 1281 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 1281 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1281 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2015	2016	2017	2018	2019	2015–2019
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
HRSA Activities:						
Authorization Level	12	12	12	12	12	60
Estimated Outlays	2	9	11	12	12	46
CDC Activities:						
Authorization Level	8	8	8	8	8	40
Estimated Outlays	3	7	8	8	8	33

	By fiscal year, in millions of dollars—					
	2015	2016	2017	2018	2019	2015–2019
Other Activities:						
Estimated Authorization Level	*	*	*	*	*	1
Estimated Outlays	*	*	*	*	*	1
Total Changes:						
Estimated Authorization Level	21	20	20	20	20	101
Estimated Outlays	6	16	19	20	20	80

Notes: HRSA = Health Resources and Services Administration; CDC = Centers for Disease Control and Prevention.
* = less than $500,000.
Components might not sum to totals because of rounding.

Basis of estimate: Most of the activities authorized under H.R. 1281 would be carried out by the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC). For this estimate, CBO assumes that H.R. 1281 will be enacted before the end of fiscal year 2014. The estimate is based on historical spending patterns for similar activities and assumes that the necessary amounts will be appropriated near the beginning of each fiscal year.

HRSA activities

H.R. 1281 would reauthorize grant programs that promote screening of newborns and children for heritable disorders for fiscal years 2015 through 2019. It also would reauthorize funding for HRSA activities that provide information regarding heritable disorders in newborns and children to individuals, health professionals, and federal officials. The Congress appropriated $12 million for those programs in fiscal year 2014. The legislation would authorize the appropriation of about $12 million a year for fiscal years 2015 through 2019. CBO estimates that implementing such provisions would cost $46 million over the 2015–2019 period, assuming appropriation of the specified amounts.

CDC activities

The legislation also would reauthorize programs within the CDC to promote quality in clinical laboratories that test for heritable diseases and authorize surveillance activities relating to heritable disorders. The Congress appropriated $7 million to CDC's newborn screening program for fiscal year 2014. The bill would authorize the appropriation of $8 million annually over the 2015–2019 period. CBO estimates that implementing those provisions would cost $33 million over the 2015–2019 period. In addition, H.R. 1281 would mandate that CDC's national contingency plan for newborn screening be updated at least every five years, but CBO estimates those costs would be insignificant.

Other activities

The bill would direct multiple agencies of the Department of Health and Human Services (HHS) to continue to collaborate in order to make recommendations for collecting, analyzing, and making data available on heritable disorders. CBO estimates that such activities would cost less than $500,000 over the 2015–2019 period, assuming the availability of appropriated funds.

In addition, H.R. 1281 would direct the Government Accountability Office (GAO) and HHS to submit reports to the Congress.

GAO would report on the timeliness of newborn screening for heritable disorders, and the Secretary of HHS would report on the ongoing activities related to newborn screening authorized by the bill and their associated costs. CBO estimates that these reports would cost about $1 million over the 2015–2019 period.

Pay-As-You-Go considerations: None.

Intergovernmental and Private-Sector Impact: H.R. 1281 contains no intergovernmental or private-sector mandates as defined in UMRA. State and local governments that participate in newborn and child screening programs could benefit from funds authorized in the bill.

Estimate prepared by: Federal Costs: Santiago Vallinas and Lisa Ramirez-Branum; Impact on State, Local, and Tribal Governments: J'nell L. Blanco; Impact on the Private Sector: Samuel Trachtman.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 1281 establishes or reauthorizes a program of the Federal government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 1281 would not specifically direct a rulemaking within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; Table of Contents

Section 1 provides the short title of "Newborn Screening Saves Lives Reauthorization Act of 2014."

Section 2. Improved newborn and child screening and followup for heritable disorders

Section 2 requires eligible entities to assist in providing health care professionals and newborn screening personnel with education and training in: new technologies related to newborn screening; understanding the importance of timeliness of collection, delivery, receipt, and screening of specimens; and sharing medical information with providers and families.

Section 3. Evaluating the effectiveness of newborn and child screening and followup programs

Section 3 provides that grants established under section 1110 of the Public Health Service Act (42 U.S.C. 33b–9) are for demonstration programs that evaluate the effectiveness, including with respect to timelines, of screening and follow-up services in reducing the morbidity and mortality caused by heritable disorders in newborns and children. The section also requires demonstration programs to evaluate and assess specified matters related to the treatment of newborns and children at risk of heritable disorders.

Section 4. Advisory Committee on Heritable Disorders in Newborns and Children

Section 4 amends the Advisory Committee on Heritable Disorders in Newborns and Children to provide for technical assistance to individuals and organizations regarding submissions to the uniform screening panel and to provide for the review of nominations prior to their submission. In addition, the Advisory Committee's model decision-matrix for newborn screen expansion would include the cost of such expansion, and the recommendations to enhance, expand, or improve the Secretary's ability to reduce the mortality or morbidity from heritable disorders may include follow-up activities necessary to achieve best practices in rapid diagnosis and appropriate treatment in the short-term, information on the cost and incidence of testing for conditions for which there is no existing treatment, and the timeliness of collection, delivery, receipt, and screening of specimens to be tested for heritable disorders in newborns in order to ensure rapid diagnosis and follow-up.

Section 4 also amends process for decisions on recommendations. The time for the Secretary to adopt the recommendations of the Advisory Committee is reduced from 180 to 120 days. If the Secretary is unable to make a determination within the 120-day period, the Secretary must provide to the Advisory Committee and Congress an explanation and a plan of action for consideration of such pending recommendations. The Advisory Committee would have 9 months from the date on which the Advisory Committee referred the nominated condition to the review workgroup to review and vote on the condition.

Section 4 also provides that the Advisory Committee would have to meet at least 4 times each year and shall continue to operate through the end of fiscal year 2019. If the Advisory Committee is not extended beyond 2019, it may be deemed an advisory committee established by the President or an officer of the Federal Government for the purposes of the Federal Advisory Committee Act.

Section 5. Clearinghouse of newborn screening information

Section 5 requires the clearinghouse to maintain current information on quality indicators to measure performance of newborn screening and the number of conditions for which screening is conducted in each State, and to disseminate evidence-based guidelines related to conditions detected by newborn screening. Finally, the section amends the non-duplication requirements to ensure that the Secretary's activities to establish and maintain a central clearinghouse of information on newborn screening will minimize duplication and supplement, not supplant, existing information sharing efforts.

Section 6. Laboratory quality and surveillance

Section 6 requires that the Secretary, acting through the Centers for Disease Control and Prevention (CDC), take into consideration the expertise of the Advisory Committee and provide, as appropriate, for the timeliness for processing newborn-screening tests. The section also authorizes the Secretary, acting through the CDC and taking into consideration the expertise of the Advisory Committee, to provide for the coordination of surveillance activities.

Section 7. Interagency Coordinating Committee on Newborn and Child Screening

Section 7 clarifies that the composition of the Interagency Coordinating Committee on Newborn and Child Screening includes the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, and the Commissioner of Food and Drugs.

Section 8. National contingency plan for newborn screening

Section 8 requires that the national contingency plan for newborn screening for use in the event of a public health emergency be updated as needed and at least every five years.

Section 9. Hunter Kelly Research Program

Section 9 amends the Hunter Kelly Newborn Screening Research Program to include (1) providing research findings and data for newborn conditions under review by the Advisory Committee to be added to the recommended uniform screening panel and (2) conducting pilot studies on conditions recommended by the Advisory Committee to ensure that screenings are ready for implementation nationwide.

Section 10. Authorization of appropriations

Section 10 consolidates the authorization of appropriations for all newborn and child screening for heritable disorders activities. The activities were authorized for $30,875,000 for fiscal year 2013, and section 10 reauthorizes the activities for $19,900,000 for each of fiscal years 2015 through 2019.

Section 11. Reports to Congress

Section 11 directs the Comptroller General of the United States to submit a report to Congress concerning the timeliness of screening for heritable disorders in newborns. The section also directs the Secretary of Health and Human Services to submit to Congress a

report on activities related to newborn screening and screening children who have or are at risk for heritable disorders within one year of the date of enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

PART A—GENETIC DISEASES

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SEC. 1109. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

(a) AUTHORIZATION OF GRANT PROGRAM.—From amounts appropriated under [subsection (j)] *section 1117* , the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the "Administrator") [and in consultation with the Advisory Committee] *and taking into consideration the expertise of the Advisory Committee* on Heritable Disorders in Newborns and Children (referred to in this section as the "Advisory Committee"), shall award grants to eligible entities to enable such entities—

(1) * * *

[(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening and training in relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;]

(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening, counseling, and training in—

(A) relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

(B) the importance of the timeliness of collection, delivery, receipt, and screening of specimens; and

(C) sharing of medical and diagnostic information with providers and families;

(3) to develop and deliver educational programs (at appropriate literacy levels) about newborn screening counseling, testing, follow-up, treatment, and specialty services to parents, families, and patient advocacy and support groups; [and]

(4) to establish, maintain, and operate a system to assess and coordinate [treatment] *followup and treatment* relating to congenital, genetic, and metabolic disorders[.]*; and*

(5) to improve the timeliness of—

(A) the collection, delivery, receipt, and screening of specimens; and

(B) the diagnosis of heritable disorders in newborns.

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(c) APPROVAL FACTORS.—An [application submitted for a grant under subsection (a)(1)] *application for a grant under this section* shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

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(h) PUBLICATION.—

(1) IN GENERAL.— An [application submitted under subsection (c)(2)] *application for a grant under this section* shall be made public by the State in such a manner as to facilitate comment from any person, including through hearings and other methods used to facilitate comments from the public.

(2) COMMENTS.— Comments received by the State after the publication described in paragraph (1) shall be addressed in the [application submitted under subsection (c)(2)] *application for a grant under this section* .

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[(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

[(1) to provide grants for the purpose of carrying out activities under subsection (a)(1), $15,000,000 for fiscal year 2009; $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013; and

[(2) to provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013.]

SEC. 1110. EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING *AND FOLLOWUP* PROGRAMS.

(a) IN GENERAL.—The Secretary shall award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness [of screening,] *, including with respect to timeliness, of screening, followup,* counseling or health care services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

(b) DEMONSTRATION PROGRAMS.—A demonstration program conducted under a grant under this section shall be designed to evaluate and assess, within the jurisdiction of the entity receiving such grant—

(1) the effectiveness of screening, [counseling, testing] *treatment, counseling, testing, followup,* or specialty services for

newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders*, including, as appropriate, through the assessment of health and development outcomes for such children through adolescence* ;

(2) the effectiveness of screening, [counseling, testing] *treatment, counseling, testing, followup,* or specialty services in accurately and reliably diagnosing heritable disorders in newborns and children *in a timely manner* ; [or]

(3) the availability of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders[.]*;*

(4) methods that may be identified to improve quality in the diagnosis, treatment, and disease management of heritable disorders based on gaps in services or care; or

(5) methods or best practices by which the eligible entities described in section 1109 can achieve in a timely manner—

(A) collection, delivery, receipt, and screening of newborn screening specimens; and

(B) diagnosis of heritable disorders in newborns.

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[(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.]

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SEC. 1111. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

(a) * * *

(b) DUTIES.—The Advisory Committee shall—

(1) * * *

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(4) provide technical assistance, as appropriate, to individuals and organizations regarding the submission of nominations to the uniform screening panel, including prior to the submission of such nominations;

(5) take appropriate steps, at its discretion, to prepare for the review of nominations prior to their submission, including for conditions for which a screening method has been validated but other nomination criteria are not yet met, in order to facilitate timely action by the Advisory Committee once such submission has been received by the Committee;

[(4)] *(6)* develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact*, including the cost* of such expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

[(5)] *(7)* consider ways to ensure that all States attain the capacity to screen for the conditions described in paragraph (3), and include in such consideration the results of grant funding under section 1109; and

[(6)] *(8)* provide such recommendations, advice or information as may be necessary to enhance, expand or improve the

ability of the Secretary to reduce the mortality or morbidity from heritable disorders, which may include recommendations, advice, or information dealing with—

(A) follow-up activities, including those necessary to [achieve rapid diagnosis] *achieve best practices in rapid diagnosis and appropriate treatment* in the short-term, and those that ascertain long-term case management outcomes and appropriate access to related services;

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(D) the availability and reporting of testing for conditions for which there is no existing treatment*, including information on cost and incidence* ;

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(J) identification of the causes of, public health impacts of, and risk factors for heritable disorders; [and]

(K) coordination of surveillance activities, including standardized data collection and reporting, harmonization of laboratory definitions for heritable disorders and testing results, and confirmatory testing and verification of positive results, in order to assess and enhance monitoring of newborn diseases[.]*; and*

(L) the timeliness of collection, delivery, receipt, and screening of specimens to be tested for heritable disorders in newborns in order to ensure rapid diagnosis and followup.

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(d) DECISION ON RECOMMENDATIONS.—

(1) IN GENERAL.— Not later than [180] *120* days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation. *If the Secretary is unable to make a determination to adopt or reject such recommendation within such 120-day period, the Secretary shall notify the Advisory Committee and the appropriate committees of Congress of such determination together with an explanation for why the Secretary was unable to comply within such 120-day period, as well as a plan of action for consideration of such pending recommendation.*

[(2) PENDING RECOMMENDATIONS.— The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment of the Newborn Screening Saves Lives Act of 2008 by not later than 180 days after the date of enactment of such Act.]

[(3)] *(2)* DETERMINATIONS TO BE MADE PUBLIC.— The Secretary shall publicize any determination on adopting or rejecting a recommendation of the Advisory Committee pursuant to this subsection, including the justification for the determination.

(3) DEADLINE FOR REVIEW.— For each condition nominated to be added to the recommended uniform screening panel in accordance with the requirements of this section, the Advisory Committee shall review and vote on the nominated condition within 9 months of the date on which the Advisory Committee

referred the nominated condition to the condition review workgroup.

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[(f) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on the date of enactment of the Newborn Screening Saves Lives Act of 2008.

[(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.]

(f) MEETINGS.—The Advisory Committee shall meet at least 4 times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

(g) CONTINUATION OF OPERATION OF COMMITTEE.—

(1) IN GENERAL.— Notwithstanding section 14 of the Federal Advisory Committee Act, the Advisory Committee shall continue to operate through the end of fiscal year 2019.

(2) CONTINUATION IF NOT REAUTHORIZED.— If at the end of fiscal year 2019 the duration of the Advisory Committee has not been extended by statute, the Advisory Committee may be deemed, for purposes of the Federal Advisory Committee Act, an advisory committee established by the President or an officer of the Federal Government under section 9(a) of such Act.

SEC. 1112. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this part as the "Administrator"), in consultation with the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish and maintain a central clearinghouse of current educational and family support and services information, materials, resources, research, and data on newborn screening to—

(1) * * *

(2) increase awareness, knowledge, and understanding of newborn diseases and screening services for expectant individuals and families; [and]

(3) maintain current [data] *information* on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as determined by the Advisory Committee under section 1111[.]*;*

(4) maintain current information on the number of conditions for which screening is conducted in each State; and

(5) disseminate available evidence-based guidelines related to diagnosis, counseling, and treatment with respect to conditions detected by newborn screening.

(b) INTERNET AVAILABILITY.—The Secretary, acting through the Administrator, shall ensure that the clearinghouse described under subsection (a)—

(1) * * *

* * * * * * *

(4) provides—

(A) * * *

* * * * * * *

(D) the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized under the [Newborn Screening Saves Lives Act of 2008] *Newborn Screening Saves Lives Reauthorization Act of 2014* ; and

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(c) NONDUPLICATION.—In [developing the clearinghouse] *carrying out activities* under this section, the Secretary shall ensure that such [clearinghouse minimizes duplication and supplements, not supplants] *activities minimize duplication and supplement, not supplant* , existing information sharing efforts.

[(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.]

SEC. 1113. LABORATORY QUALITY *AND SURVEILLANCE* .

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention [and in consultation with the Advisory Committee] *and taking into consideration the expertise of the Advisory Committee* on Heritable Disorders in Newborns and Children established under section 1111, shall provide for—

(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, *timeliness for processing such tests,* performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and

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[(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.]

(b) SURVEILLANCE ACTIVITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, may provide, as appropriate, for the coordination of surveillance activities, including—

(1) through standardized data collection and reporting, as well as the use of electronic health records; and

(2) by promoting data sharing regarding newborn screening with State-based birth defects and developmental disabilities monitoring programs.

SEC. 1114. INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

(a) * * *

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(c) COMPOSITION.—The Interagency Coordinating Committee shall be composed of the Director of the Centers for Disease Control and Prevention, [the Administrator, the Director of the Agency for Healthcare Research and Quality,] *the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs,* and the Director of the National Institutes of Health, or their designees.

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[(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.]

SEC. 1115. NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator and State departments of health (or related agencies), shall develop a national contingency plan for newborn screening for use by a State, region, or [consortia] *consortium* of States in the event of a public health emergency. *The plan shall be updated as needed and at least every five years.*

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SEC. 1116. HUNTER KELLY RESEARCH PROGRAM.

(a) NEWBORN SCREENING ACTIVITIES.—

(1) IN GENERAL.— The Secretary, in conjunction with the Director of the National Institutes of Health and taking into consideration the recommendations of the Advisory Committee, may continue carrying out, coordinating, and expanding research in newborn screening (to be known as "Hunter Kelly Newborn Screening Research Program") including—

(A) * * *

(B) experimental treatments and disease management strategies for additional newborn conditions, and other genetic, metabolic, hormonal, or functional conditions that can be detected through newborn screening for which treatment is not yet available[; and];

(C) providing research findings and data for newborn conditions under review by the Advisory Committee on Heritable Disorders in Newborns and Children to be added to the recommended uniform screening panel;

(D) conducting pilot studies on conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children to ensure that screenings are ready for nationwide implementation; and

[(C)] *(E)* other activities that would improve newborn screening, as identified by the Director.

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(c) REPORTS.—The Director is encouraged to include information about the activities carried out under this section in the biennial report required under section 403 [of the National Institutes of Health Reform Act of 2006]. If such information is included, the Director shall make such information available to be included on the Internet Clearinghouse established under section 1112.

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SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR NEWBORN SCREENING PROGRAMS AND ACTIVITIES.

There are authorized to be appropriated—

(1) to carry out sections 1109, 1110, 1111, and 1112, $11,900,000 for each of fiscal years 2015 through 2019; and

(2) to carry out section 1113, $8,000,000 for each of fiscal years 2015 through 2019.

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